IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PFIZER INC., PFIZER PHARMACEUTICALS, LLC, PFIZER IRELAND PHARMACEUTICALS, PFIZER LIMITED, and C.P. PHARMACEUTICALS INTERNATIONAL C.V., Plaintiffs and Counterclaim Defendants, v. SANDOZ Inc., Defendant and Counterclaimant.	)	Civil Action No. 09cv00742-JJF

DEFENDANT SANDOZ INC.'S ANSWER AND COUNTERCLAIMS FOR DECLARATORY RELIEF

Defendant Sandoz Inc. ("Sandoz"), hereby submits this Answer to the Complaint of Plaintiffs Pfizer, Inc.; Pfizer Pharmaceuticals, LLC; Pfizer Ireland Pharmaceuticals; Pfizer Limited; and C.P. Pharmaceuticals International C.V. (collectively "Pfizer") as follows. Sandoz denies all allegations of the Complaint except as otherwise stated below.

1. Sandoz admits that this purports to be an action for infringement of United States Patent No. 6,455,574 (the "'574 patent"). Sandoz admits that a copy of the '574 patent is attached to the Complaint as Exhibit A.

2. Sandoz admits that, on its face, the '574 patent has an issue date of September 24, 2002. Sandoz admits that the '574 patent names Jan Buch as the sole inventor, names Pfizer Inc. as the assignee, and is entitled "Therapeutic Combination."

PARTIES, JURISDICTION AND VENUE

3. Sandoz admits that Pfizer Inc. is a corporation organized and existing under the laws

of the State of Delaware and has a place of business at 235 East 42 Street, New York, New York 10017. Sandoz admits that Pfizer, Inc. is listed on the face of the '574 patent as the assignee. Sandoz is without sufficient knowledge or information to form a belief as to the truth of the remaining allegations contained in paragraph 3 of the Complaint, and on that basis denies each and every allegation contained therein.

4. Sandoz admits that Pfizer Pharmaceuticals, LLC is a limited liability company organized and existing under the laws of the State of Delaware. Sandoz is without sufficient knowledge or information to form a belief as to the truth of the remaining allegations contained in paragraph 4 of the Complaint, and on that basis denies each and every allegation contained therein.

5. Sandoz is without sufficient knowledge or information to form a belief as to the truth of the allegations contained in paragraph 5 of the Complaint, and on that basis denies each and every allegation contained therein.

6. Sandoz is without sufficient knowledge or information to form a belief as to the truth of the allegations contained in paragraph 6 of the Complaint, and on that basis denies each and every allegation contained therein.

7. Sandoz is without sufficient knowledge or information to form a belief as to the truth of the allegations contained in paragraph 7 of the Complaint, and on that basis denies each and every allegation contained therein.

8. Sandoz is without sufficient knowledge or information to form a belief as to the truth of the allegations contained in paragraph 8 of the Complaint, and on that basis denies each and every allegation contained therein.

9. Sandoz is without sufficient knowledge or information to form a belief as to the truth

of the allegations contained in paragraph 9 of the Complaint, and on that basis denies each and every allegation contained therein.

10. Sandoz is without sufficient knowledge or information to form a belief as to the truth of the allegations contained in paragraph 10 of the Complaint, and on that basis denies each and every allegation contained therein.

11. Sandoz is without sufficient knowledge or information to form a belief as to the truth of the allegations contained in paragraph 11 of the Complaint, and on that basis denies each and every allegation contained therein.

12. Sandoz admits that the '574 patent is identified in the FDA publication *Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book") as covering Pfizer's Caduet® products. Sandoz denies the remaining allegations of paragraph 12.

13. Sandoz admits the allegations of paragraph 13.

14. Sandoz admits that this action purports to arise under the Patent Laws of the United States, 35 U.S.C. §§ 1 *et seq.* and that this Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338.

15. Sandoz admits that it is licensed to distribute pharmaceuticals in the state of Delaware and is in the business of making and selling generic pharmaceutical products for sale throughout the United States, including Delaware.

16. Sandoz admits that it is registered with the Delaware Board of Pharmacy as a "Distributor/Manufacturer CSR" and "Pharmacy-Wholesale." Sandoz denies the remaining allegations of paragraph 16.

17. Sandoz admits that it filed Abbreviated New Drug Application ("ANDA") No. 91-462 ("Sandoz's ANDA") seeking approval from the Food and Drug Administration ("FDA") to

engage in the commercial manufacture, sale, and use of products containing amlodipine besylate and atorvastatin calcium as the active ingredients in amounts of 5 mg/80 mg and 10 mg/80 mg, respectively (the "Sandoz ANDA Products"). Sandoz further admits that under 35 U.S.C. § 271(e)(2)(A), its submission to the FDA of Abbreviated New Drug Application No. 91-462 constitutes a statutory act of infringement. Sandoz denies that the '574 patent is valid, enforceable, or would be infringed by the manufacture, use, offer for sale, sale, or importation of a generic product containing amlodipine besylate and atorvastatin calcium as the active ingredients and, on that basis, Sandoz denies the remaining allegations of paragraph 17.

18. Sandoz admits that it sent a Confidential Notice Letter, dated August 24, 2009, to Pfizer informing Pfizer of the filing of Sandoz's ANDA, as required by 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95 (the "ANDA Notice Letter"). The ANDA Notice Letter was sent from Sandoz's New Jersey facility. Sandoz denies the remaining allegations of paragraph 18.

19. Sandoz admits that it has been a party in other litigation in the District of Delaware where it has asserted counterclaims. Sandoz denies the remaining allegations of paragraph 19.

20. Sandoz admits that part of its business of providing quality, cost effective generic medications to the citizens of the United States involves protecting through litigation its right to produce such products. Sandoz denies the remaining allegations of paragraph 20.

21. Sandoz admits that it has answered Complaints and asserted counterclaims in District of Delaware Case Nos. 1:07-cv-807-JJF, 1:08-cv-317-JJF, 1:08-cv-534-KSH, 1:09-cv-033-JJF, 1:09-cv-215-GMS, and 1:09-cv-310-GMS. Sandoz avers that it waived its affirmative defense of personal jurisdiction in those specific actions voluntarily, as is its right to do, without conceding that personal jurisdiction over Sandoz exists for all purposes or as alleged in this Action. Sandoz denies the remaining allegations of paragraph 21.

22. Sandoz admits that it did not contest personal jurisdiction for purposes of Case No. 1:09-cv-310-GMS. Sandoz denies the remaining allegations of paragraph 22.

23. Sandoz admits that it admitted to conducting business in the State of Delaware in its Answer in Case No. 1:08-cv-317-JJF. Sandoz, however, made no admission that such conduct subjected it to personal jurisdiction in the State of Delaware, and denied having any systematic business contacts with the State of Delaware. Sandoz denies the remaining allegations of paragraph 23.

24. Sandoz admits that it is in the business of manufacturing generic pharmaceuticals and distributing those pharmaceuticals throughout the United States. Sandoz further admits that in Case No. 1:09-cv-033-JJF Sandoz admitted to distributing and selling generic pharmaceuticals in the United States generally and in the State of Delaware specifically.

25. Sandoz admits that, as required by the rules of this Court, it engaged Delaware counsel to represent it on previous occasions, and continues to be represented by Delaware counsel in ongoing litigation. Sandoz denies the remaining allegations of paragraph 25.

26. Paragraph 26 contains legal conclusions that require no response. To the extent paragraph 26 contains any factual allegations, Sandoz denies them.

ANSWER TO CLAIM FOR RELIEF

27. Sandoz hereby incorporates by reference each and every allegation set forth in paragraphs 1 through 26 as if fully set forth herein.

28. Sandoz admits that it filed Abbreviated New Drug Application No. 91-462 seeking approval from the FDA to engage in the commercial manufacture, sale, and use of products containing amlodipine besylate and atorvastatin calcium as the active ingredients in amounts of 5 mg/80 mg and 10 mg/80 mg, respectively. Sandoz further admits that it sent a Confidential

Notice Letter, dated August 24, 2009, to Pfizer informing Pfizer of the filing of Sandoz's ANDA, as required by 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95 (the "ANDA Notice Letter") and that Pfizer attached a copy of the Confidential ANDA Notice Letter to its complaint as Exhibit B without making any effort to redact any of the proprietary information contained therein and in clear disregard of the ANDA Notice Letter's confidentiality provisions and Sandoz's expectation of confidentiality. Sandoz denies the remaining allegations of paragraph 28.

29. Sandoz admits that the ANDA Notice Letter contained an "Offer of Confidential Access" as provided by 21 U.S.C. § 355(j)(5)(C)(i)(III).

30. Sandoz denies that the "Offer of Confidential Access" contained any impermissible restrictions on access, and denies the remaining allegations of paragraph 30.

31. Sandoz admits that the ANDA Notice Letter addressed, among others, the '574 patent and explained why it is invalid.

32. Sandoz admits that it sent Pfizer the ANDA Notice Letter to provide notice pursuant to 21 U.S.C. § 355(b)(3) that Sandoz had filed the Sandoz ANDA seeking approval to manufacture, use, offer for sale, and sell generic versions of Pfizer's drug products sold under the Caduet® brand in 5 mg/80 mg and 10 mg/80 mg strengths. Sandoz further admits that this letter provided notice of Sandoz's paragraph IV certification that the '574 patent is invalid, unenforceable, and/or not infringed by the Sandoz ANDA Products, and that this letter provided a statement of the factual and legal bases for Sandoz's assertions of invalidity, unenforceability, and/or noninfringement. Sandoz admits that the ANDA Notice Letter did not provide a separate explanation for why each claim of the '574 patent is not infringed by the Sandoz ANDA Products. Sandoz denies the remaining allegations of paragraph 32.

33. The ’574 patent speaks for itself. Sandoz admits that, on its face, the expiration date of the ’574 patent is August 11, 2018.

34. Sandoz admits that, under 35 U.S.C. § 271(e)(2)(A), its submission to the FDA of Abbreviated New Drug Application No. 91-462 to obtain approval for a product containing amlodipine besylate and atorvastatin calcium as the active ingredients only constitutes a statutory act of infringement. Sandoz denies that the ’574 patent is valid, enforceable, or would be infringed by the manufacture, use, offer for sale, sale, or importation of a generic product containing amlodipine besylate and atorvastatin calcium as the active ingredients and, on that basis, Sandoz denies the allegations in paragraph 34.

35. Sandoz denies the allegations in paragraph 35.

AFFIRMATIVE DEFENSES

Without admitting or implying that Sandoz bears the burden of proof as to any of them, Sandoz asserts, on information and belief, the following affirmative defenses:

FIRST AFFIRMATIVE DEFENSE
(’574 patent - Invalidity)

1. The ’574 patent, and each claim thereof, is invalid for failing to comply with the requirements of the patent laws of the United States, particularly with regard to one or more of the requirements specified in Sections 101, 102, 103 and/or 112 of Title 35 of the United States Code.

SECOND AFFIRMATIVE DEFENSE
(’574 patent – Noninfringement)

2. Sandoz and the Sandoz ANDA Products do not infringe any valid enforceable claim of the ’574 patent, directly or indirectly, either literally or under the doctrine of equivalents.

THIRD AFFIRMATIVE DEFENSE
(Failure to State a Claim)

3. The Complaint fails to state a claim upon which relief can be granted.

FOURTH AFFIRMATIVE DEFENSE
(No Personal Jurisdiction)

4. The Complaint fails to allege a basis for personal jurisdiction over Sandoz, and Sandoz is not subject to personal jurisdiction in this District.

FIFTH AFFIRMATIVE DEFENSE
(Improper Venue)

5. The Complaint fails to allege a sufficient basis for finding venue proper in this District.

SIXTH AFFIRMATIVE DEFENSE
(Miscellaneous Reservation of Rights)

6. Sandoz presently asserts the above defenses without the benefit of full discovery and investigation, and reserves the right to supplement or amend these affirmative defenses as necessary.

COUNTERCLAIMS

Defendant and Counterclaimant Sandoz Inc. ("Sandoz") submits these Counterclaims, which could be found compulsory, against Pfizer Inc.; Pfizer Pharmaceuticals, LLC; Pfizer Ireland Pharmaceuticals; Pfizer Limited; and C.P. Pharmaceuticals International C.V. (collectively "Pfizer"). Sandoz asserts these Counterclaims without consenting to personal jurisdiction in this forum, or waiving its right to contest personal jurisdiction, and expressly reserves all rights and defenses.

PARTIES

1. Sandoz is a Colorado corporation with its principal place of business at 506

Carnegie Center, Suite 400, Princeton, New Jersey 08540. Sandoz's Broomfield, Colorado, manufacturing facility spans 600,000 square feet and has an oral-dosage capacity of 10 billion units, making it the largest such manufacturing facility in the world.

2. Pfizer Inc. is a corporation organized and existing under the laws of the State of Delaware and has a place of business at 235 East 42nd Street, New York, New York 10017.

3. According to the Complaint in this case, Pfizer Pharmaceuticals, LLC is a limited liability company organized and existing under the laws of the State of Delaware with offices at 235 East 42nd Street, New York, New York 10017. Pfizer Pharmaceuticals, LLC is a wholly owned subsidiary of Pfizer Inc.

4. According to the Complaint in this case, Pfizer Limited is a company incorporated under the laws of England with offices at Ramsgate Road, Sandwich, Kent, England CT13 9NJ. Pfizer Limited is a wholly owned, indirect subsidiary of Pfizer Inc.

5. According to the Complaint in this case, Pfizer Ireland Pharmaceuticals is a partnership, organized and existing under the laws of Ireland, with registered offices at Pottery Road, Dun Laoghaire, Co. Dublin, Ireland. Pfizer Ireland Pharmaceuticals is a wholly owned, indirect subsidiary of Pfizer Inc.

6. According to the Complaint in this case, C.P. Pharmaceuticals International C.V. is a limited partnership (commanditaire vennootschap) organized under the laws of the Netherlands, having its registered seat in Rotterdam, and registered at the trade register held by the Chamber of Commerce in Rotterdam, the Netherlands, under number 24280998.

JURISDICTION AND VENUE

7. These Counterclaims arise under the patent laws of the United States, 35 U.S.C. §§ 1 *et seq*. and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

8. This Court has subject matter jurisdiction over these Counterclaims pursuant to 28

U.S.C. §§ 1331 and 1338, 21 U.S.C. § 355(j)(5)(C)(i) and 35 U.S.C. § 271(e)(5).

9. By filing the Complaint in this case Pfizer has submitted to personal jurisdiction and venue in this District. Sandoz continues to contest personal jurisdiction and venue.

FACTUAL BACKGROUND

10. On September 24, 2002, the United States Patent and Trademark Office issued the '574 patent, entitled "Therapeutic Combination," to Jan Buch. According to the information on the face of the patent, it was assigned to Pfizer Inc.

11. According to the Complaint in this case, Pfizer Limited and Pfizer Ireland Pharmaceuticals are beneficial owners of the '574 patent.

12. According to the Complaint in this case, C.P. Pharmaceuticals International C.V. is a wholly owned subsidiary of Pfizer Inc. and the exclusive licensee of Pfizer Limited under the '574 patent.

13. According to the Complaint in this case, the exclusive licensee of the '574 patent is Pfizer Pharmaceuticals, LLC by assignment from C.P. Pharmaceuticals International C.V.

14. According to the Complaint in this case, Pfizer has all the right, title, and interest in the '574 patent and the right to sue for infringement thereof.

15. Upon information and belief C.P. Pharmaceuticals International C.V. is the owner of approved New Drug Application ("NDA") No. 21-540 for formulations comprised of the active ingredients amlodipine besylate and atorvastatin calcium, including 5 mg/80 mg and 10 mg/80 mg compositions. Pfizer sells drug products under NDA 21-540 in the United States, including in this District, under the registered name Caduet®.

16. Pfizer has listed or caused to be listed in the FDA's *Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluation* (the "Orange Book") the '574 patent for formulations comprised of the active ingredients amlodipine besylate and atorvastatin calcium,

including dosage combinations comprising 5 mg/80 mg and 10 mg/80 mg of the active ingredients.

17. By listing, or causing to be listed, the ’574 patent in the Orange Book, Pfizer claims that formulations comprised of the active ingredients amlodipine besylate and atorvastatin calcium, including dosage combinations comprising 5 mg/80 mg and 10 mg/80 mg, infringe one or more claims of said patent.

18. Sandoz submitted Abbreviated New Drug Application No. 91-462 (the “Sandoz ANDA”) to the FDA seeking approval to manufacture and market amlodipine besylate and atorvastatin calcium tablets, 5 mg/80 mg and 10 mg/80 mg compositions, (the “Sandoz ANDA Products”).

19. The Sandoz ANDA included a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a “Paragraph IV certification”) stating that the Sandoz ANDA Products do not infringe any valid, enforceable claim of, among others, the ’574 patent.

20. On August 24, 2009, pursuant to 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95, Sandoz sent a Confidential Notice Letter (the “Sandoz Notice Letter”) to Pfizer informing Pfizer of the filing of the Sandoz ANDA and explaining the basis of Sandoz’s Paragraph IV certification.

21. By October 7, 2009, Pfizer filed actions in the District of Delaware and the District of Colorado asserting that the filing of the Sandoz ANDA was an act of infringement of the ’574 patent.

22. More than 45 days have elapsed since Sandoz provided notice of the filing of the Sandoz ANDA to Pfizer.

23. Sandoz intends to market the Sandoz ANDA Products in the United States as soon

as legally permissible after approval of the 91-462 ANDA in light of potential third party exclusivity rights.

24. An actual and justiciable controversy exists between Pfizer and Sandoz regarding validity and infringement of the ’574 patent.

FIRST COUNTERCLAIM
(Declaratory Judgment of Invalidity of the ’574 patent)

25. Sandoz hereby incorporates by reference each and every allegation set forth in paragraphs 1 through 35 of the Answer, 1 through 6 of the Affirmative Defenses, and 1 through 24 of these Counterclaims.

26. The ’574 patent, and each claim thereof, is invalid for failing to comply with the requirements of the patent laws of the United States, particularly with regard to one or more of the requirements specified in Sections 101, 102, 103 and/or 112 of Title 35 of the United States Code.

27. There exists an actual controversy between Sandoz and Pfizer regarding the validity of the ’574 patent, and a judicial declaration of invalidity is necessary and appropriate at this time.

SECOND COUNTERCLAIM
(Declaratory Judgment of Noninfringement of the ’574 patent)

28. Sandoz hereby incorporates by reference each and every allegation set forth in paragraphs 1 through 35 of the Answer, 1 through 6 of the Affirmative Defenses, and 1 through 27 of these Counterclaims.

29. Sandoz and the Sandoz ANDA Products do not infringe any valid enforceable claim of the ’574 patent, directly or indirectly, either literally or under the doctrine of equivalents.

30. There exists an actual controversy between Sandoz and Pfizer regarding whether

Sandoz infringes the '574 patent, and a judicial declaration of noninfringement is necessary and appropriate at this time.

PRAYER FOR RELIEF

WHEREFORE, Sandoz asks the Court to enter judgment in its favor and grant the following relief:

1. Dismiss with prejudice the entirety of Pfizer's Complaint;

2. Dismiss all remedies and relief sought by Pfizer in the Complaint;

3. Declare that Sandoz has not infringed and is not infringing any valid enforceable claim of the '574 patent;

4. Declare every claim of the '574 patent invalid;

5. Find this an exceptional case and award Sandoz its costs, attorneys' fees, and expenses pursuant to 35 U.S.C. § 285; and

6. Grant such other and further relief as the Court may deem just and proper.

Dated: October 26, 2009

/s/ Richard K. Herrmann

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